City of Austin/Travis County
Emergency Services Clinical Partnership

Office of the Medical Director

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22 January 2004

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 1994N-0418 Reclassification of Automated External Defibrillators

To Whom It May Concern:

I am writing this letter in support of the above-referenced reclassification of automated external defibrillators (AEDs) and to urge the FDA to move forward with the reclassification of these devices.

I am the Medical Director of the City of Austin / Travis County EMS System and the Chairperson of the Governor's EMS & Trauma Advisory Council for the State of Texas. I am also an Assistant Clinical Professor of Emergency Medicine at the University of Texas Southwestern School of Medicine. I have been actively involved with the American Heart Association at the Local, State and National level and have been a strong supporter of Public Access Defibrillation programs throughout my career. I am familiar with the recent medical literature regarding AEDS and have participated in several papers on Public Access Defibrillation. Based on my clinical experience with AEDs and the community response to cardiac arrest patients, I strongly believe that reclassification of the AED to Class II is appropriate and desirable for public health.

There is no question that AEDs today provide significant clinical benefit in the fight to reduce the mortality from Sudden Cardiac Arrest (SCA). AEDs are a vital tool in the chain of survival for SCA victims. Extensive clinical experience has shown that AEDs are effective in increased survival from SCA. As such, I believe it is important that we should continue to work together to improve public access to AEDs. It's good policy and frankly, good medicine.

It is also my experience that risks and adverse events associated with AEDs are rare and minimal compared to clinical benefits they provide. Interestingly, I was a co-author of the original report of an inappropriate shock by an AED in an EMS System (Ornato JP, Shipley JB, Powell RG, Racht EM: Inappropriate electrical countershocks by an automated external defibrillator. Ann Emerg Med 1992; 21(10):1278-82).

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As a result, I have followed the literature & the reports of AED issues for the past 14 years. If safety were an issue, organized medicine, Governmental EMS Systems and those involved in resuscitation science would have clearly stopped the rapid promulgation of these life-saving devices long ago.

The simplicity of the devices, the dramatic impact of an earlier shock on both morbidity and mortality and the widespread lay acceptance of the implementation of Public Access Defibrillation programs all support the vital importance of this technology. We have many tears of data, experience and scientific scrutiny to suggest that it is safe and indeed desirable to do everything we can as partners to increase access to AEDs.

In summary, I strongly support the reclassification of the AED as a Class II device based on a review of the extensive record, the literature, my clinical experience and the standard safeguards developed to address the potential device risks. I appreciate the opportunity to share my views and am willing to help in any way I can with this process.

Thanks...

Sincerely,

Edward M. Racht, MD
Medical Director